

# Product & Regulatory Associates, L.L.C.

September 29, 2021

Hope Johnson (PM-21)  
Document Processing Desk (REGFEE)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

**Subject: AG33037 C 3.4FL Fungicide  
EPA File Symbol 2749-XXX  
Application for Pesticide Registration for a New Product**

**PRIA Category: R301 New End-Use Product, Substantially Similar in  
Composition and Use to a Registered Product with Product  
Chemistry Data**

**PRIA Milestone Tracking E-mail Notification: [jwrightch@comcast.net](mailto:jwrightch@comcast.net)**

Dear Hope Johnson:

On behalf of Aceto Life Sciences, LLC, I am transmitting this application for pesticide registration of AG33037 C 3.4FL Fungicide to the U.S. Environmental Protection Agency.

This new end-use product registration contains dodine, PC Code 44301 as the sole active ingredient. It is an aqueous flowable concentrate (FL) formulation containing dodine at a nominal concentration of 39.6 % w/w or 3.4 lbs. active per gallon. This end use formulation needs to be diluted with water prior to spray applications for the control of the diseases listed on the proposed label.

The source of the active ingredient is linked to the registered technical product source listed on the Confidential Statement of Formula and Formulator's Exemption forms.

The complete product chemistry data for this formulation to support this registration application are provided as listed below. In some of the data, the title reference is Dodine 3.4FL, AG33037. This formulation is identical to the AG33037 C 3.4FL Fungicide described here.

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Since this product is substantially similar to Syllit Flow Fungicide, EPA Reg. No. 55260-6, the acute toxicology data for that product is used to support this product as listed on the Data Matrix forms.

The label use sites are from the referenced substantially similar dodine formulation, Syllit Flow Fungicide.

The PRIA Category is R301, new end-use product from a registered source of active ingredient with product chemistry data and use sites on a substantially similar registered product. The fee is \$1,992.00.

The registration application request contains the following enclosed materials:

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Administrative Documents

- Transmittal
- Application for Pesticide Registration (EPA Form 8750-1)
- Cover letter
- PRIA IV Fee Confirmation 26TFEKR
- Authorized Representative letter
- Confidential Statement of Formula (EPA Form 8750-4)  
Basic dated 9/10/21
- Formulator's Exemption Statement (EPA Form 8570-27)
- Certificate with Respect to Citation of Data (EPA Form 8570-34)
- Data matrix private and public copies (EPA Form 8570-35)
- Proposed label
  - 002749-00XXX.20210910.AG33037 C 34FL Proposed Label.pdf

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**MRID 51701101** *AG33037 C 3.4FL Fungicide, Product Chemistry, Group A: Product Identity and Composition*, OCSPP Guidelines 830.1500, 830.1600, 830.1650, 830.1670 & 830.1750, John F. Wright, Product & Regulatory Associates, LLC, September 10, 2021, Study Number 21-PRA-Aceto-220, 76 pp.

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**MRID 51701102** *Dodine 3.4FL AG33037, Physical and Chemical Characteristics: Color, Physical State, Odor, Flammability, pH, Viscosity and Density/Relative Density*, OPPTS Guidelines 830.6302, 830.6303, 830.6304, 830.6315, 830.7000, 830.7100 & 830.7300, Catherine Wo, Product Safety Labs, August 30, 2017, Laboratory Study Number 46028, 15 pp.

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**MRID 51701103** *Dodine 3.4FL, AG33037: Enforcement Analytical Method for Determination of Dodine by High Performance Liquid Chromatography*, OPPTS Guideline 830.1800, Catherine Wo, Product Safety Labs, December 27, 2017, Laboratory Study No.46027 EAM, 14 pp.

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**MRID 51701104** *AG33037 C 3.4FL Fungicide: Physical and Chemical Properties – Waiver Requests of Product Chemistry Data*, OCSPP Guideline Series 830, John Wright, Product & Regulatory Associates, LLC, September 10, 2021, Study No. 21-PRA-Aceto-217, 6 pp.

If you have any question in regard to this matter, feel free to contact me at (609) 841-8288 or JWrightCH@comcast.net.

Sincerely,



John F. Wright  
Product & Regulatory Associates, LLC  
Authorized Representative of Aceto Life Sciences, LLC

cc: Fred Trudwig, Jr., Aceto